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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/727,292	12/02/2003	Shinichi Tsuzaki	JCLA12308	5325
23900	7590	05/09/2006	EXAMINER	
J C PATENTS, INC. 4 VENTURE, SUITE 250 IRVINE, CA 92618			MCCORMICK EWOLDT, SUSAN BETH	
			ART UNIT	PAPER NUMBER

1655

DATE MAILED: 05/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/727,292	Applicant(s) TSUZAKI ET AL.	
	Examiner S. B. McCormick-Ewoldt	Art Unit 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 February 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,7,8 and 11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,7,8 and 11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendment of February 24, 2006 is hereby acknowledged and entered.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Upon further consideration, the advisory action dated April 10, 2006 has been vacated and finality of the office action dated November 29, 2005 has been withdrawn.

Claims Pending

Applicant has cancelled claims 3-6 and 9-10. Claims 1-2, 7-8 and 11 are pending.

Claim Rejections - 35 USC § 102

Applicant's arguments, see page 13, filed February 24, 2006, with respect to the rejection of 35 USC § 102 (b) have been fully considered and are persuasive. The rejection of 35 USC § 102 has been withdrawn.

Claim Rejections - 35 USC § 103

Claims 1 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shen *et al.* (US 6,013,771) in view of Lee (US 6,413,557).

Shen discloses producing an isoflavone rich protein material from vegetable matter, which is extracted with an aqueous extractant and then is separated from insoluble material to produce an extract containing isoflavones and protein (column 2, lines 45-52). The vegetable material used is obtained from soybean materials (column 3, lines 30-33). The pH of the aqueous extractant is preferably about pH 6.0 to about pH 10 (column 4, lines 7-8).

Shen does not disclose wherein the temperature is 0°C to 17°C.

Lee discloses soybean hypocotyls have high a concentration of isoflavones (column 5, lines 6-9). The hypocotyls axis contains lipids (column 4, lines 63-65).

One of ordinary skill in the art would have been motivated to use isoflavones from soybean hypocotyls because of the high concentration of isoflavones in soybean hypocotyls and to separate them for a protein rich soluble composition. It was clear from Shen that isoflavone rich protein material from soybean material can be extracted with an aqueous extractant, and

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then separated from insoluble material to produce an extract containing isoflavones and protein. Shen also discloses the pH of the aqueous extractant is about pH 6.0 to about pH 10. It was further clear from Lee that soybean hypocotyls have a high concentration of isoflavones. Therefore, one of ordinary skill in the art would have had a reasonable expectation to use an aqueous extractant to extract isoflavones from soybean hypocotyls, due to their high concentration of isoflavones.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Although none of the references disclose the amounts of protein or lipid content, one of ordinary skill in the art would have been motivated to vary the temperature, as the level of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to vary the pH and temperature levels to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient levels would have been obvious at the time of Applicant's invention.

Claims 1 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shen *et al.* (US 6,013,771) in view of Obata *et al.* (US 6,444,239).

Shen *et al.* disclose producing an isoflavone rich protein material from vegetable matter, which is extracted with an aqueous extractant and separated from insoluble material to produce an extract containing isoflavones and protein (column 2, lines 45-52). The vegetable material used is obtained from soybean materials (column 3, lines 30-33). The pH of the aqueous extractant is preferably about pH 6.0 to about pH 10 (column 4, lines 7-8).

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Shen *et al.* do not disclose wherein the temperature is 0°C to 17°C.

Obata *et al.* (US 6,444,239) disclose that isoflavone precipitate can be freeze-dried (see Example 2).

One of ordinary skill in the art would have been motivated to use isoflavones from soybean hypocotyls because of the high concentration of isoflavones in soybean hypocotyls and to separate them for a soluble composition. It was clear from Shen that isoflavone rich protein material from soybean material can be extracted with an aqueous extractant, separated from insoluble material to produce an extract containing isoflavones and protein. Shen also discloses the pH of the aqueous extractant is about pH 6.0 to about pH 10. It was further clear from Obata that isoflavone precipitate can be freeze-dried. Although neither reference disclose using temperatures levels between 0°C to 17°C, one of ordinary skill in the art would have been motivated to vary the temperature in a composition because optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal temperature levels to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of temperature levels would have been obvious at the time of Applicant's invention.

Therefore, one of ordinary skill in the art would have had a reasonable expectation to use an aqueous extractant to extract isoflavones from soybean material and freeze-dried.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Claims 1-2, and 7-8 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mizutani (JP-10298175) in view of Bryan *et al.* (US 5,994,508) in view of Obata (US 6,444,239).

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Mizutani (JP-10298175) discloses using soybean hypocotyls to obtain an extraction that contains water-soluble isoflavones, where the isoflavone content is 20% and the insolubles are eliminated by centrifugation. In the extraction of the isoflavones, the pH ranges from 2 to 8 and temperatures range from 5°C to 40°C (whole document).

Mizutani does not disclose wherein extraction without a protease.

Bryan *et al.* (US 5,994,508) disclose using a process of extracting soybean isoflavones with the temperature typically from about 30°F to about 90°F (i.e. -1°C to 32°C) (column 5, lines 30-35, 53-57 and claims 1, 3-4, 6).

Obata *et al.* (US 6,444,239) disclose that isoflavone precipitate can be freeze-dried (see Example 2).

The references taken together disclose a method for the extraction isoflavones from soybean hypocotyls. A person of ordinary skill in the art would be motivated to combine the teachings of Mizutani, Bryan and Obata because Mizutani discloses the pH ranges and temperature of extracting soybean isoflavones from soybean hypocotyls and Bryan discloses extracting isoflavones without the use of a protease and Obata discloses the isoflavone precipitate can be freeze-dried. Based on this reasonable expectation of success one of ordinary skill in the art would have been motivated to make modifications to Mizutani, Bryan and Obata.

Although none of the references disclose the amounts of protein or lipid content, one of ordinary skill in the art would have been motivated to vary the pH level and temperature as the level of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to vary the pH and temperature levels to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient levels would have been obvious at the time of Applicant's invention.

One of ordinary skill in the art would have been motivated to vary the pH level and temperature as the level of a specific ingredient in a composition is clearly a result effective

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parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to vary the pH and temperature levels to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient levels would have been obvious at the time of Applicant's invention.

From the teaching of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Summary

No claim is allowed.

Correspondence

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Susan B. McCormick-Ewoldt whose telephone number is (571) 272-0981. The Examiner can normally be reached Monday through Thursday from 6:00 a.m. to 4:30 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiners' supervisor, Terry McKelvey, can be reached at (571) 272-0775. The official fax number for the group is (571) 273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

sbme



CHRISTOPHER R. TATE
PRIMARY EXAMINER